DEPARTMENTS OF LABOR, HEALTH AND HUMAN SERVICES, EDUCATION, AND RELATED AGENCIES APPROPRIATIONS FOR FISCAL YEAR 2006

WEDNESDAY, MARCH 16, 2005

U.S. SENATE,
SUBCOMMITTEE OF THE COMMITTEE ON APPROPRIATIONS,
Washington, DC.

The subcommittee met at 10:42 a.m., in room SD–138, Dirksen Senate Office Building, Hon. Arlen Specter (chairman) presiding.

Present: Senators Specter, Craig, DeWine, Harkin, Kohl, Murray, and Durbin.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

OFFICE OF THE SECRETARY

STATEMENT OF HON. MICHAEL O. LEAVITT, SECRETARY

ACCOMPANIED BY:

KERRY WEEMS, ACTING ASSISTANT SECRETARY FOR BUDGET, TECHNOLOGY, AND FINANCE

JENNIFER YOUNG, ASSISTANT SECRETARY FOR LEGISLATION

OPENING STATEMENT OF SENATOR ARLEN SPECTER

Senator SPECTER. Good morning. The Subcommittee on Labor, Health and Human Services, Education, and Related Agencies will now proceed. We have established a record for starting these hearings on time so that we do not keep busy people waiting or people who are not busy waiting. But as I had said a moment or two ago, the floor manager had scheduled my amendment for increasing the budget of the subcommittee by $2 billion, $1.5 billion for the National Institutes of Health, and $500 million for Education. We just concluded the argument and came right over here and have had a very brief discussion with the distinguished Secretary.

We do welcome you here, Mr. Secretary. You come to this office with a very, very distinguished record with the governorship of Utah and Administrator of the Environmental Protection Agency, and a very distinguished record before public service. We look forward to working with you.

My full statement will be made a part of the record and in view of our late arrival I will make only a very few introductory remarks. As I had commented to the Secretary when we moved the hearing from 9:30 to 10:30, that has compressed my schedule, and

I've asked Senator DeWine to be here to take over the chairmanship here at 11.

But the only introductory comments that I will make are the daunting tasks which we all have. We have a budget for the subcommittee which is several billion dollars under what it was last year. We have a 3.5 percent cut for the Department of Labor. We have a $500 million cut for Education. There is a proposed budget for your Department, Mr. Secretary, for $62.4 billion, which is a reduction of almost $1.3 billion, and that's not calculating the inflation rate. So that means it's another $2 billion on top of a billion, probably $3.5 billion.

PREPARED STATEMENT

But you come to this job with a great reputation for being a wonder worker, so we will watch your work and we will work with you. Now I yield to my distinguished colleague, the seamless Senator Harkin.

[The statement follows:]

PREPARED STATEMENT OF SENATOR ARLEN SPECTER

This morning, the subcommittee on Labor, Health and Human Services, Education, and Related Agencies will discuss the President'S $62.4 billion 2006 budget request for the Department of Health and Human Services, which is $1.3 billion below the fiscal year 2005 level. We are Delighted to have before us the distinguished Secretary of Health and Human Services, the honorable Michael O. Leavitt.

This subcommittee is pleased to see several shared priorities funded in the fiscal year 2006 budget, including $303 million over the fiscal year 2005 level for Community Health Centers and $203 million over the fiscal year 2005 level for the Strategic National Stockpile to protect our Nation against bioterrorism.

However, this subcommittee is concerned by the small 0.5 percent increase in Biomedical Research Funding at the National Institutes of Health—which is a cut in real terms. Also of concern are the large cuts in funding of many HHS programs, including the complete elimination of 35 programs.

Mr. Secretary, I know that you can appreciate the difficult tradeoffs that this subcommittee will need to negotiate in the coming months as we balance the competing pressures of biomedical research, worker protection programs and continued investment in our Nation's youth. Mr. Secretary, I look forward to working with you as we craft an appropriations bill that maintains our commitment to fiscal restraint while preserving funding for high priority programs.

OPENING STATEMENT OF SENATOR TOM HARKIN

Senator HARKIN. Thank you very much, Mr. Chairman. I will follow your lead and not make a full opening statement. Again, thank you, Mr. Chairman, for your leadership on the floor, on NIH, to get that funding back up. It just—at a time when we're making so many great breakthroughs, when we've finished mapping the human gene, when we've gotten a lot of young people now more interested in basic research because of the doubling of NIH, now it seems like, well, we did that and now we don't have to do anything more.

But that was just catch-up ball. We were just playing catch-up ball. Now we've caught up, now all of a sudden we're moving back again. So I just want to compliment my friend and my chairman for taking the lead on the floor on this.

Just a couple—three things, Mr. Secretary. Again, welcome you to your first appearance before our subcommittee. Congratulations on your new position. Like the chairman, we have met personally

and I've just heard a lot of good things about you, and your reputation is sterling, I can say that.

I just—a couple of comments on the budget, eliminating services for some 25,000 kids on Head Start. That's very bothersome. The community services block grant program. Now, you might say, well, we're continuing some of the things like LIHEAP and Head Start, things like that, but if you don't have the people that do it, how does it get done? Community services block grants being zeroed out is just—I don't know what we—what could be behind that.

There's one other thing, the systems change grant. Your predecessor was very strong and the President was, the President spoke about this in the past, better check the record on the system change grants. This has to do with the court case—what am I thinking about—Olmstead case. The Supreme Court decision said that people with disabilities must live in the least restricted environment.

Well, we've built up a system of nursing homes in this country that are still needed for some obviously. But for a lot of people with disabilities who can get to the community, they need these system change grants. Your predecessor and the President has spoken strongly about this and something called money follows the person, but there's nothing in this budget for it.

So, again, just a few of those things I wanted to point to, but lest you think I think everything's bad in this budget, I compliment you for the increase in the community health centers. This is one thing that serves—the $300 million proposed increase is welcome, it's needed. They do a great job I'm sure in your State, mine, all over the country. So that is one right spot in this budget that will have our full support, you can be assured.

Thank you, Mr. Secretary. Thank you, Mr. Chairman.

Senator SPECTER. Thank you, Senator Harkin. We welcome you again, Mr. Secretary, and the floor is yours. We look forward to your testimony. Your full statement will be made a part of the record and our practice is to ask you to summarize to the extent you can, leaving the maximum amount of time for questions and answers. We have a very good attendance for the subcommittee today.

SUMMARY STATEMENT OF HON. MICHAEL O. LEAVITT

Secretary LEAVITT. Thank you, Mr. Chairman, and Senator Harkin. I will in the spirit of efficiency summarize quickly. As you indicated, the budget—the overall budget is $642 billion. That's a 10 percent increase over last year. Much of that will be in the Medicare Modernization Act and its implementation.

MEDICAID

This subcommittee, as you pointed out, is $62.4 billion, and it's a lot of money, and we're here to do our best to defend how in fact we will do it efficiently. I hope we have a chance today to talk about Medicaid. Forty six million Americans are served by it. It's rigidly inflexible. The Governors are desperate to have some change so they can maintain coverage for people who have it and hopefully provide coverage for some who don't.

I hope we have a chance to talk some about the implementation of the Medicare Modernization Act. That's the main event for 2005 in my opinion for HHS, and we're working hard to make certain that it's done well. We all have a substantial stake in its implementation.

Community health centers is a favorite of mine to talk about too, Senator Harkin, and I'm hopeful that we'll get a chance to talk more about that.

Homeland defense has been very much on my mind, as I suspect it is everyone else's, $4.3 billion to continue our work there, $600 million of it into strategic stockpiles. Our goal is to have needed medications within 12 hours of every man, woman, and child in the United States.

NIH, a subject I know that's very important to you, Senator, and to others, $28.8 billion, $1.8 billion of that again in biodefense. The flu has become an area of major concern to me, particularly the—as we begin to see the avian flu become more prominent in Asia. I hope we have a chance to talk about our preparation there.

The President has emphasized faith-based initiatives also, his hope that reauthorization of the Welfare Act of 1996 could be accomplished this year. This budget will support the administration's belief in both faith-based and also in abstinence education. The budget does support Head Start with $6.9 billion.

PREPARED STATEMENT

A subject I hope we get a chance to talk about is Health IT. That's an issue that I intend to take on personally.

It's what I believe to be a lean but strong and fiscally responsible budget, and I'm looking forward to more conversation.

[The statement follows:]

PREPARED STATEMENT OF HON. MICHAEL O. LEAVITT

Good morning Mr. Chairman, Ranking Member Harkin, and members of the Subcommittee. I am honored to be here today to present to you the President's fiscal year 2006 Budget for the Department of Health and Human Services (HHS). The President and I share an aggressive agenda for the upcoming fiscal year, in which HHS advances a healthier, stronger America while upholding fiscal responsibility and good stewardship of the People's money.

In his February 2nd State of the Union Address, the President underscored the need to restrain spending in order to sustain our economic prosperity. As part of this restraint, it is important that total discretionary and non-security spending be held to levels proposed in the President's fiscal year 2006 Budget. The budget savings and reforms in the President's Budget are important components of achieving the President's goal of cutting the budget deficit in half by 2009 and we urge the Congress to support these reforms. The President's fiscal year 2006 Budget includes more than 150 reductions, reforms, and terminations in non-defense discretionary programs, 19 of which affect HHS programs. The Department wants to work with the Congress to achieve these savings.

The President's health agenda leads us towards a Nation of healthier Americans, where health insurance is within the reach of every American, where American workers have a comparative advantage in the global economy because they are healthy and productive, and where health technology allows for a better health care system that produces fewer mistakes and better outcomes at lower costs. The fiscal year 2006 HHS budget advances this agenda.

The fiscal year 2006 HHS budget funds the transition towards a health care system where informed consumers will own their personal health records, health savings accounts, and health insurance. It enables seniors and people with disabilities to choose where they receive long-term care and from whom they receive it. Equally important, it builds on the Department's Strategic Plan and enables HHS to foster

strong, sustained advances in the sciences underlying medicine, in public health, and in social services.

To support our goals, President Bush proposes outlays of $642 billion for HHS, a 10 percent increase over fiscal year 2005 spending, and more than a 50 percent increase over fiscal year 2001 spending. The proposed fiscal year 2006 HHS budget increase accounts for almost two-thirds of the entire proposed federal budget increase in fiscal year 2006. The overall discretionary portion of the President's HHS budget totals $67 billion in budget authority and $71 billion in program level funding. The discretionary portion of programs covered by this subcommittee totals $62.4 billion in budget authority and $65.3 billion in program level funding.

The Department will direct its resources and efforts in fiscal year 2006 towards:
—Providing access to quality health care;
—Enhancing public health and protecting America;
—Supporting a compassionate society; and
—Improving HHS management.

The President and the Department considered a number of factors in constructing the fiscal year 2006 budget, including the need for spending discipline and program effectiveness to help cut the deficit in half over four years. Specifically, the budget decreases funding for lower-priority programs and one-time projects, consolidates or eliminates programs with duplicative missions, reduces administrative costs, and makes government more efficient. For example, the budget requests no funding for the Community Services Block Grant that was unable to demonstrate results in Program Assessment Rating Tool evaluation. Instead, the Administration proposes to focus economic and community development activities through a more targeted and unified program to be administered by the Department of Commerce. It is due to this scrutiny that I am certain the proposed increases in spending will enable the Department to continue to provide for the health, safety, and well-being of our People.

Americans enjoy the finest health care in the world. This year's budget provides opportunities to make quality health care more affordable and accessible to millions more Americans. Our challenge is to ensure that everyone has access to health insurance.

PROVIDING ACCESS TO QUALITY HEALTH CARE

MMA Implementation

The next important step toward meeting this challenge is the implementation of the Medicare Modernization Act (MMA), including the Medicare Prescription Drug Benefit and the new Medicare Advantage regional health plans. The Centers for Medicare and Medicaid Services (CMS) administrative budget request of $3.2 billion includes $560 million for implementing the new voluntary drug benefit that begins January 1, 2006, enhanced health plan choices in Medicare Advantage, as well as numerous other MMA provisions. The new prescription drug benefit will cost $58.9 billion in 2006 and will be financed through beneficiary premiums and general revenue. The President's Budget also proposes $75 million for program integrity efforts to combat fraud and abuse in the new Part D and Medicare Advantage programs.

February 15, 2004 was the final date for plans to submit Medicare Advantage 2005 applications to provide coordinated care plans, including local preferred provider organizations (PPOs). The deadline for stand-alone prescription drug plans, new Medicare Advantage contractors, and regional PPOs to submit their "Notice of Intent to Apply" was February 18, 2005. CMS has received significant initial interest from potential prescription drug plan sponsors to offer the Medicare drug benefit throughout the Nation. In addition, insurance plans have expressed interest in significantly expanding Medicare Advantage service areas providing more options to Medicare beneficiaries.

Medicaid

The President and I are also committed to improving Medicaid. Medicaid provides health insurance for more than 46 million Americans, but as you are all aware, States still complain about overly burdensome rules and regulations, and the state-federal financing system remains prone to abuse.

This year, for the first time ever, States spent more on Medicaid than they spent on education. Over the next ten years, American taxpayers will spend nearly $5 trillion on Medicaid in combined state and federal spending. The Department plans to make sure tax dollars are used more efficiently by building on the success of the State Children's Health Insurance Program (SCHIP) and waiver programs that allow states the flexibility to construct targeted benefit packages, coordinate with private insurance, and extend coverage to higher income and non-traditional Med-

icaid populations. Additionally, we estimate that proposals included in the President's Budget to strengthen program integrity and ensure that Medicaid doesn't overpay for drugs will create $60 billion in new savings over a ten-year period.

The President plans to expand coverage for the key populations served in Medicaid and SCHIP by spending $15.5 billion on targeted activities over ten years. The President's Budget includes several proposals to provide coverage, including the Cover the Kids campaign to enroll more eligible uninsured children in Medicaid and SCHIP. In addition, the extension of the Qualified Individual and transitional medical assistance programs will ensure coverage is available to continue full payment (subject to a spending limit) of Medicare Part B premiums for qualified individuals, and provide coverage for families that lose eligibility for Medicaid due to earnings from employment. The Department projects that over 50 million individuals will be covered by Medicaid and SCHIP in fiscal year 2006, at a federal cost of $198 billion.

Community Health Centers

In addition to expanding access through Medicaid and SCHIP, the President's Budget builds on the Department's aggressive efforts to help those who are uninsured or underinsured by expanding the good work of community health centers. These centers provide quality, compassionate care to the patients who need our help the most, regardless of their ability to pay.

The President's Budget requests $2 billion, a $304 million increase from fiscal year 2005, to fund community health centers. This request completes the President's commitment to create 1,200 new or expanded sites to serve an additional 6.1 million people by 2006. By the end of fiscal year 2006, the Health Centers program will deliver high quality, affordable health care to over 16 million patients at more than 4,000 sites across the country. Health centers are effectively targeted to eliminate health disparities and provide a range of essential services. In 2006, health centers will serve an estimated 16 percent of the Nation's population who are at or below 200 percent of the federal poverty level. Almost forty percent of Health Center patients have no health insurance and 64 percent are racial or ethnic minorities. In addition, the President has set a new goal to help every poor county in America that lacks a community health center by establishing a community health center in counties that can support one, or a rural health center. The President's Budget includes $26 million to fund 40 new health centers in high poverty counties.

Ryan White/HIV

Our request also includes approximately $18 billion for domestic AIDS care, treatment, research, and prevention. We are committed to the reauthorization of the Ryan White CARE Act treatment programs, consistent with the President's reauthorization principles of prioritizing lifesaving services including HIV/AIDS medications and care; providing more flexibility to target resources; and ensuring accountability by measuring progress. The President's Budget requests a total of $2.1 billion for Ryan White activities, including $798 million for lifesaving medications through the AIDS Drug Assistance Program.

Providing Access to Quality Health Care: The Administration's Comprehensive Plan

These projects and reforms, as well as those at other Departments, cooperate to extend health care and insurance to millions of people. For instance, the President proposes to spend more than $125.7 billion over ten years to expand insurance coverage to millions of Americans through tax credits, purchasing pools, and Health Savings Accounts. The proposed Traditional Health Insurance Tax Credit would pay for 90 percent of the cost of the premium of standard coverage, up to a maximum of $1,000 for an individual, and $3,000 for a family of four. The proposed Health Insurance Tax Credit for those with Health Savings Accounts (HSAs) would allow individuals to use a portion of the credit to purchase a high-deductible health plan while putting the remaining portion of the credit in an HSA. The Administration also proposes legislation that would that would allow small employers, civic groups, and community organizations to band together and leverage purchasing power to negotiate lower-priced coverage for their employees, members, and their families through Association Health Plans (AHPs). As opposed to previous proposals that limited AHPs to small businesses, this proposal also applies to private, non-profit, and multi-state entities outside the workplace.

Thanks to the comprehensive nature of this vision, workers are already investing money tax-free for medical expenses through Health Savings Accounts, Americans have increasing flexibility to accumulate savings and to change jobs when they wish, and more Americans are accessing high-quality health care. We estimate that 12 to 14 million additional people will gain health insurance over the next ten years.

Bioterrorism Preparedness

Since 2001, your support for HHS's bioterrorism efforts has been unwavering. As a result we have made tremendous strides in protecting our Nation from various threats. The HHS fiscal year 2006 budget builds upon these achievements to strengthen our ability to minimize the number of casualties that would occur as a result of a bioterrorist attack, or other attack with weapons of mass destruction. From 2001 to 2005, HHS invested nearly $15 billion to prepare our Nation's health systems. The fiscal year 2006 budget requests $4.3 billion to continue this work, a 1,500 percent increase from the 2001, pre-9/11 level.

The fiscal year 2006 request places the highest priority on those programs that address readiness issues for which there is a unique federal role. These include the new mass casualty initiative, the Strategic National Stockpile (SNS), and National Institutes of Health (NIH) research on next-generation countermeasures.

HHS has a responsibility to lead public health and medical services during major disasters and emergencies. Toward this end, the President's Budget would invest $70 million in a new effort to develop federal mass casualty treatment capacity that can be rapidly deployed and staffed to supplement the surge capacity being developed at the state and local level. Of this amount, $50 million, financed through the SNS, will be used to procure and manage the mass casualty treatment units. The Medical Reserve Corps will be expanded by $12.5 million to support the enrollment, training, and credentialing of volunteers that could be deployed in the event of a national emergency. A new $7.5 million effort will fund the development of a secure database that can consolidate healthcare provider credentialing information from federal, state, and non-government sources for quick retrieval in a major emergency. This activity will be fully coordinated with the state-based Emergency System for Advance Registration of Volunteer Healthcare Personnel that the Health Services and Resources Administration (HRSA) sponsors.

The Strategic National Stockpile's goal is to provide state and local governments the pharmaceuticals and supplies they would need to minimize casualties from a bioterrorist attack or other major public health emergency within 12 hours. The budget requests a total of $600 million for the SNS, an increase of $203 million above the fiscal year 2005 enacted level (including the $50 million for mass casualty treatment units discussed earlier). The Administration has continued to reassess the stocks that are needed to best protect the American population. As a result, by the end of fiscal year 2006, the SNS will have sufficient antibiotics to provide prophylaxis to up to 60 million Americans exposed to the anthrax organism. The SNS will set up the highly specialized cold storage capacity needed for the IND vaccines procured through BioShield. Substantial funds will also be used to replace medications that are losing potency, and to maintain the capacity needed to deploy assets to any part of the Nation within hours of the detection of an event.

Our Nation's ability to detect and counter bioterrorism ultimately depends on the state of biomedical science, and NIH will continue to ensure full coordination of research activities with other federal agencies in this battle. The President's Budget includes $1.8 billion for NIH biodefense research efforts, a net increase of $56 million. When this is adjusted for non-recurring extramural construction in fiscal year 2005, NIH biodefense research activities grow by $175 million, or 11 percent, over fiscal year 2005. Included in this total is a $50 million initiative budgeted in the Public Health and Social Services Emergency Fund to develop new medical countermeasures against chemicals that could be used as weapons of mass destruction.

HHS continues to have a strong commitment to preparing States and local public health departments and hospitals to prepare against public health emergencies and acts of bioterrorism. From fiscal year 2002 to fiscal year 2005, $5.4 billion has been invested in this work through the Centers for Disease Control (CDC) and HRSA's ongoing state and local preparedness programs. The fiscal year 2006 budget includes $1.3 billion more for this work, increasing the cumulative total to $6.7 billion.

Influenza

Since the H5N1 strain of avian influenza first appeared in 1997, public health officials have grown increasingly concerned about the possibility that a pandemic strain will emerge that could cause an additional 90,000 to 300,000+ deaths in the United States. Avian influenza has reappeared in Southeast Asia again this year, indicating that the virus has become endemic. The fiscal year 2006 budget continues to expand HHS's efforts to be prepared in the event this or another deadly influenza strain changes in a way that makes it easily communicable from person to person.

Since fiscal year 2001, HHS has increased its direct expenditures related to influenza vaccine from $42 million to $439 million in fiscal year 2006, in addition to in-

surance reimbursement payments through Medicare. The fiscal year 2006 budget includes targeted efforts to ensure a stable supply of annual influenza vaccine, to improve access to influenza vaccine for children and Medicare beneficiaries, to develop the surge capacity that would be needed in a pandemic, and to improve the response to emerging infectious diseases before they reach the United States.

Increasing the use of annual influenza vaccinations will both reduce annual morbidity/mortality, and make the Nation better prepared in the event of a pandemic. CDC estimates that 185 million people should receive annual immunizations but fewer than half of that number have ever been immunized in a given year. The President's Budget seeks to increase annual immunization rates by both making sure an ample supply is manufactured each year and working to ensure it is used. The President's Budget includes several initiatives within CDC's two immunization programs to expand the production of bulk monovalent and finished influenza vaccine for the 2006/7 influenza season. CDC will invest $70 million in new resources to build vaccine stockpiles. First, CDC will set aside $40 million in new mandatory Vaccines for Children (VFC) budget authority for a stockpile of finished pediatric influenza vaccine that can be used in the event of a late-season surge in demand; the first ever stockpile was purchased for the winter of 2004/5. Second, CDC's discretionary Section 317 program will invest $30 million in contracts to get manufacturers to make additional bulk monovalent vaccine over and above the amounts the companies expect to use for the 2006/7 season. This added bulk vaccine will be available to be turned into finished vaccine if other producers experience problems, or if an unusually high demand for vaccine is anticipated. Bulk vaccine not used for the 2006/7 season will be kept for potential use the following year. Commonly, one or two of the strains in the trivalent influenza vaccine remain the same from one year to the next.

HHS is also continuing its efforts to expand annual influenza immunizations. The Section 317 program will also use increased funding of $20 million over fiscal year 2005 to purchase an estimated two million doses of influenza vaccine for the 2006/7 influenza season to help states expand vaccination for children. Centers for Medicare and Medicaid Services has taken steps to ensure that physicians have appropriate incentives to improve vaccination rates. Since 2002, the Medicare reimbursement rate for the administration of influenza vaccine has increased more than four times, from an average of $3.98 in 2002 to $18.57 in 2005. The reimbursement rate for the vaccine product also increased, from $8.02 to $10.10.

To ensure sufficient vaccine can be made quickly in a pandemic, the Nation needs to develop the ability to surge domestic vaccine production as soon as scientists determine that a pandemic strain has emerged. The President's Budget increases the Department's investment in pandemic preparedness efforts by $21 million, for a total of $120 million in fiscal year 2006. This increase will be used to develop the year-round domestic surge vaccine production capacity that would be needed in a pandemic; this added surge capacity could also be used to respond to unexpected problems in the production of annual vaccines. It will finance contracts with vaccine manufacturers to develop and license influenza vaccines using new production techniques and establishing a domestic manufacturing capability. HHS will continue to ensure a year-round supply of specialized eggs needed for domestic production of currently licensed vaccines. Manufacturers will be encouraged to license and implement new processing and other technologies to improve vaccine yields from both new cell culture vaccines and existing egg-based vaccines. In addition, HHS will sponsor the development and licensing of antigen-sparing strategies that would increase the number of individuals who could be vaccinated from a given amount of bulk vaccine product. Finally, the President's Budget maintains the flexibility to redirect these funds to initiate pandemic vaccine production at any time a pandemic appears imminent.

To improve our Nation's long-term preparedness and enhance the annual vaccine supply, NIH will invest approximately $120 million in influenza-related research nearly six times the fiscal year 2001 level. Research areas include new cell culture techniques for flu vaccine production, which complements the advanced development; vaccines for potential pandemic strains, including H5N1; next-generation antiviral drugs; rapid, ultra-sensitive diagnostic devices to detect influenza virus infection; and ways to make flu vaccine more effective among the elderly.

These research and advanced development efforts will be complemented by expanding funding for CDC's Global Disease Detection initiatives by $12 million, from $22 million to $34 million in fiscal year 2006, to improve our ability to prevent and control outbreaks before they reach the United States.

Childhood Immunization

The President's Budget includes proposed legislation in the mandatory VFC program to improve low-income children's access to routine immunizations that I believe members of this committee should strongly support. This proposed legislation would ensure that all children have access to all routinely recommended vaccines regardless of cost such as the newly-approved meningococcal conjugate vaccine. This legislation would enable any child who is currently entitled to receive VFC vaccines to receive them at state and local public health clinics. There are hundreds of thousands of underinsured children who are entitled to VFC vaccines, but can receive them only at HRSA-funded health centers and other Federally Qualified Health Centers. When these children go to a state or local public health clinic, they are unable to receive vaccines through the VFC program and the State may decide not to use scarce discretionary dollars to provide newer, more expensive vaccines. This legislation will expand access to routine immunizations by eliminating this barrier to coverage and will help States meet the rising costs of new and better vaccines. As modern technology and research has generated new and better vaccines, that cost has risen dramatically. For example, when the pneumococcal conjugate vaccine became available, it increased the cost of vaccines to fully-immunize a child by approximately 80 percent. A new meningococcal vaccine has recently been approved that will further raise the cost to fully immunize a child making this legislation even more important.

Focus on the Future—Health Information Technology and NIH

Our fiscal year 2006 budget was also constructed with the knowledge that health information technology will improve the practice of medicine and make it more efficient. For example, the rapid implementation of secure and interoperable electronic health records will significantly improve the safety, quality, and cost-effectiveness of health care. To implement this vision, we are requesting an investment of $125 million. The Office of the National Coordinator for Health Information Technology would spend $75 million to provide strategic direction for development of a national interoperable health care system, and to address barriers to the widespread adoption of electronic health records. The Agency for Health Care Quality and Research continues to direct $50 million to accelerate the development, adoption, and diffusion of interoperable information technology in a range of health care settings.

Equally important, major advances in knowledge about life sciences, especially the sequencing of the human genome, are opening dramatic new opportunities for biomedical research. Heretofore un-imagined prospects for more precisely predicting individual susceptibility to disease and responses to medication are now close at hand, as are new approaches to diagnosing, preventing, and treating disease and disability. These advances have been driven by the investments in research made by the National Institutes of Health (NIH), the world's largest and most distinguished organization dedicated to medical science.

The fiscal year 2006 budget request for NIH of $28.8 billion seeks to capitalize on the opportunities these investments have created to further improve the health of the Nation. The NIH budget is built upon and reflects the tremendous growth in biomedical research spending in recent years. In fiscal year 2006, over $24 billion of the $28.8 billion requested for NIH will flow out to the extramural community, which supports work by more than 200,000 research personnel affiliated with approximately 3,000 university, hospital, and other research facilities across our great Nation. These funds will support nearly 39,000 investigator-initiated research project grants in fiscal year 2006, including an estimated 9,463 new and competing awards. NIH will also fund close to 1,400 research centers, over 17,400 research trainees, and much more.

In fiscal year 2006, NIH will also continue to implement the Roadmap for Medical Research by spending a total of $333 million, an increase of $98 million over fiscal year 2005, on initiatives to target research gaps and opportunities that no single NIH institute could solve alone. The budget request also emphasizes efforts to enhance collaborations for multidisciplinary neuroscience research and accelerate efforts to develop and evaluate vaccines against HIV/AIDS. Within this total, NIH will also increase funding to address critical requirements in biodefense, including a targeted $50 million research effort to develop new medical countermeasures for chemicals that can be used as weapons of mass destruction.

SUPPORTING A COMPASSIONATE SOCIETY

Faith-Based and Community Organizations

As part of the Administration's Faith-Based and Community Initiative, the HHS fiscal year 2006 budget maintains a commitment to strengthen the capacity of faith-

based and community organizations, including the Access to Recovery program, the Compassion Capital Fund, the Mentoring Children of Prisoners program, and Maternity Group Homes.

The toll of drug abuse on the individual, family, and community is both significant and cumulative. Abuse may lead to lost productivity and educational opportunity, lost lives, and to costly social and public health problems, including HIV/AIDS, domestic violence, child abuse, and crime. Through the Access to Recovery program, HHS will assist States in expanding access to clinical treatment and recovery support services and allow individuals to exercise choice among qualified community provider organizations, including those that are faith-based. This program recognizes that there are many pathways of recovery from addiction. Through Access to Recovery individuals are assessed, given a voucher for appropriate services, and provided with a list of providers from which they can choose. Fourteen States and one tribal organization were awarded Access to Recovery funding in fiscal year 2004, the first year of funding for the initiative. The funded entities have identified target populations that include youth, individuals involved with the criminal justice system, women, individuals with co-occurring disorders, and homeless individuals. The President's Budget increases support for the Access to Recovery initiative by 50 percent, for a total of $150 million, and will support a total of 22 States participating.

The Compassion Capital Fund advances the efforts of community and charitable organizations, including faith-based organizations, to increase their effectiveness and enhance their ability to provide social services where they are needed. The President's Budget includes $100 million, an increase of $45 million in support of the Compassion Capital Fund.

Within this program, the President has proposed a new focus on young Americans that will include support for programs that help youth overcome the specific risk of gang influence and involvement. This three-year, $150-million initiative will provide grants to faith-based and community organizations targeting youth ages 8–17, and will help some of America's communities that are most in need. These organizations will provide a positive model for youth one that respects women and rejects violence.

Abstinence

Expanding abstinence education programs are also part of a comprehensive and continuing effort of the Administration, because they help adolescents avoid behaviors that could jeopardize their futures. Last year, HHS integrated abstinence education activities with positive youth development efforts at the Administration for Children and Families (ACF), by transferring the Community-Based Abstinence Education program and the Abstinence Education Grants to States to ACF. The HHS fiscal year 2006 budget expands activities to educate adolescents and parents about the health risks associated with early sexual activity and provide them with the tools needed to help adolescents make healthy choices. The programs focus on educating adolescents ages 12 through 18, and create a positive environment within communities to support adolescents' decisions to postpone sexual activity. Where appropriate, the programs also offer mentoring, counseling, and adult supervision to promote abstinence with a focus on those groups which are most likely to bear children out of wedlock. A total of $206 million, an increase of $39 million, is requested for these activities.

Head Start

The Head Start program helps ensure that children, primarily in low-income families, are ready to succeed in school by supporting their social and cognitive development. Head Start programs also engage parents in their child's preschool experience by helping them achieve their own educational, literacy, and employment goals. The HHS fiscal year 2006 budget of $6.9 billion will provide comprehensive child development services to 919,000 children. This level includes an increase of $45 million to support the President's initiative to improve Head Start by funding nine state pilot projects to coordinate state preschool, child care, and Head Start in a comprehensive system of early childhood programs for low-income children.

Temporary Assistance for Needy Families

It has been three years since President Bush first proposed his strategy for reauthorizing TANF and the other critical programs included in welfare reform. During this time, the issues have been debated thoroughly but the work has not been completed and States have been left to wonder how they should proceed. We believe it is important to finish this work as soon as possible and set a strong, positive course for helping America's families. The proposal is guided by four critical goals that will transform the lives of low-income families: strengthen work, promote healthy families, give States greater flexibility, and demonstrate compassion to those in need.

Administration on Aging

The President's Budget requests a total of $1.4 billion in the Administration on Aging for programs that serve the most vulnerable elderly Americans, who otherwise lack access to healthy meals, preventive care, and other supports that enable them to remain in their home communities and out of nursing facilities. It also continues investments in program innovations to test new models of home and community-based care.

IMPROVING HHS MANAGEMENT

The President's Management Agenda (PMA) provides a framework to improve the management and performance of HHS. HHS has taken significant steps to institutionalize its focus on results and achieve improved program performance that is important to the HHS mission and the American taxpayer.

Budget and Performance Integration (BPI) aims to improve program performance and results by ensuring that performance information is used to inform funding and management decisions. For fiscal year 2006, HHS operating divisions produced their first "performance budgets" which combine budget and performance information in a single document. With this new format the Department moved from the traditional approach of presenting separate budget justifications and performance plans to the use of one integrated document to present both budget and performance information. This move also enhanced the availability and use of program and performance information to inform the budget process.

HHS has made significant steps in its implementation of the President's five government-wide management initiatives. The Program Assessment Rating Tool (PART) is an important component of the Budget and Performance Integration initiative and is used to assess program performance and improve the quality of performance information. Sixty-five HHS programs were reviewed in the PART process between fiscal year 2004 and fiscal year 2006. HHS consolidated 40 personnel offices into four Human Resources Centers, which became operational in January 2004, and is planning several upcoming projects to support Human Capital strategic management. Since the start of the competitive sourcing initiative, HHS has competed almost 25 percent of its commercial activities, resulting in increased efficiencies and savings for the American taxpayer. For example, HHS anticipates gross savings of $55 million from studies completed in fiscal year 2004, which will be redirected to mission critical activities at HHS. This year, HHS will focus on structuring competitions to maximize efficiencies and savings, as well as implement a savings validation plan. HHS also implemented several processes to improve the financial performance of the Department, such as streamlining and accelerating the annual financial reporting process and combining annual audited financial statements with program performance information in the Department's Performance and Accountability Report. HHS is also continues to implement the Unified Financial Management System throughout the Department. More than 95 percent of HHS' information systems have certified and accredited security plans. Finally, HHS has been working to achieve a more mature Enterprise Architecture that links performance to strategic, capital planning, and budget processes.

Over the past four years, the Administration has worked diligently with the Department to make America and the world healthier. I am proud to build on the HHS record of achievements. For the upcoming fiscal year, the President and I share an aggressive agenda for HHS that advances a healthier, stronger America while upholding fiscal responsibility and good stewardship of the People's money. I look forward to working with Congress as we move forward in this direction. I am happy to answer any questions you may have.

MEDICAID PROTECTION

Senator SPECTER. Well, thank you very much, Mr. Secretary, for many things, most recently brevity.

Mr. Secretary, I begin with a question on the Medicaid. It has been a topic among Senators. It serves people who are desperately in need of medical attention. There is a projected reduction which is represented at 1 percent, but in the out-years it grows exponentially. You come with three terms as Governor of Utah, so you've been in the Governor's role. The Governors are very concerned about Medicaid.

Senator Smith of Oregon has offered an alternative proposal to take a closer look at it on a commission, not satisfied with the review which has been made so far, which has—could have more depth. We can always study more. Of course it involves some delay. But how will the recipients of Medicaid at the present time be protected with the proposal which you have backed?

Secretary LEAVITT. Senator, that's the right question in my mind. How do we protect the coverage of people who are currently being served, and how in fact can we expand the reach of Medicaid? It's currently serving some 46 million Americans. But some of them are in jeopardy because the program has such rigid inflexibility that States are by the nature of that inflexibility being forced to look at diminishing the coverage substantially or eliminating the coverage of many optional groups.

A couple of points. One is, if there is any perception that Medicaid is being cut, I would like to suggest that is not correct. The Medicaid budget will grow by in excess of 7 percent over the next 10 years. We'll see almost $5 trillion spent at the end of that 10 years. We'll see $900 billion more from the Federal side be put into Medicaid. It is a rapidly growing program.

What the budget does reflect is a desire to see it increase at a slightly slower rate. The Governors I believe are, as I've spoken with them, some—I think I've had conversations now with 38 of them about this subject in direct and personal ways. There are a series of reforms that they're anxious to see that provide flexibilities that will allow them to continue the coverage of many who they believe are imperiled.

The reforms are quite common sense in my mind. One is to reduce the amount that's paid for prescription drugs, not to reduce the number of people served by them or to reduce the number of drugs they can receive, but to change the way in which they are paid for. Medicaid would be widely known as the best payer in the business. They pay higher costs for prescription drugs than Medicare or for that matter most private plans. This would propose a statute change that would allow them to essentially pay the same rate as Medicare Part B will pay.

The second reform is caring for what's known as an asset spenddown where people have learned to give their assets to their children so that the State can pay for their Medicaid, and Governors would like to see that changed.

The third is in being able to provide a series of co-pays among those who are in higher income brackets served by Medicaid. Governors are interested to see Medicaid recipients become cost-conscious consumers in the same way that others are required.

The fourth would be really a celebration of SCHIP, to use SCHIP more broadly to provide more flexibility in constructing benefit plans of again mostly mothers and children in higher income brackets that would provide the ability to serve more.

The last is an important reform, and that is as the number of elderly served by Medicaid increases and will clearly increase in the future, there's a desire to in essence liberate Medicaid from exclusive use of nursing homes. We'd like to be able to have people served in their homes and in communities. It's more efficient, and frankly that's where they want to be served.

So, Senator, those are the reforms that are on the table. They are reflected in the budget as a budget reduction, but only because they provide flexibility that in my judgement almost all the States will be using in health care in different ways to preserve the coverage of those who might lose it otherwise.

Senator SPECTER. Mr. Secretary, let me compliment you on finishing your answer within 2 seconds of the allotted time which I have. That plus your opening statement on brevity gets you off to a very, very good start with this subcommittee.

Secretary LEAVITT. Thank you.

Senator SPECTER. I'm now going to turn the gavel over to my distinguished colleague, Senator DeWine, to relieve me on the chairmanship. Thank you very much.

Secretary LEAVITT. Thank you, Senator.

Senator DEWINE [presiding]. Senator Harkin.

IOWA ARMY AMMUNITION PLANT

Senator HARKIN. Thank you very much, Mr. Chairman. Mr. Secretary, we visited earlier. We talked about briefly, a month or so ago, I forget when it was, about the situation at the Iowa Army ammunition plant that had to do with workers who had worked there for years in a nuclear weapons facility there.

A little background. Several years ago a worker had contacted me there because of all the cancers that had been happening to people, asked me to look into this. I contacted the Department of the Army who informed me that they had never assembled nuclear weapons there, and so I went out on a limb and told this guy that he must be mistaken, and he never gave up, Mr. Anderson never gave up. He came back and we finally found out that in fact they had been assembling nuclear weapons there for many, many years, and many of the workers there were exposed to high levels of radiation, had no knowledge of this. They were sworn to secrecy. Many of them never talked to doctors, never talked to anyone, because of this oath of secrecy they had taken.

Well, this has all gone through a lot of hearings and processes and stuff. Senator Bond and I have managed to win four votes on this. But basically the NIOSH Advisory Board on Radiation and Worker Health voted seven-zip, seven to nothing, to provide automatic compensation for former nuclear weapons workers at the Iowa Army ammunition plant.

Now, under the law they are then to notify you by letter of their decision. Under the law you then have 30 days whether to approve or disapprove of this, and then of course Congress then can step in depending upon what the decision is. Have you received any—that notification yet?

Secretary LEAVITT. No.

Senator HARKIN. Well, this may be an unfair question, but I'll ask it. Do you have any explanation as to why you have not received an official notification?

Secretary LEAVITT. I don't. I've read accounts that the vote took place as you have indicated. I'm aware that—but I can't reconcile why they haven't. When I do receive it, we'll obviously act in a way that's timely.

Senator HARKIN. Well, Mr. Secretary, I—well, I wrote them a letter yesterday along with others to Mr. Howard, director of NIOSH, and Mr. Paul Ziemer, chairman of the Advisory Board on Radiation and Worker Health, because I didn't know, I really didn't know if they had transmitted or not. So I wrote them a letter saying, if you haven't, please do it. So I hope that we can find out why it is that they have not forwarded this, because these workers have been waiting a long time. It was a—wasn't even a—as I said, wasn't even a close vote, seven to nothing. So I'm hopeful we can move ahead on that.

The other thing I wanted to talk about just for the record, Mr. Secretary, it was reported yesterday that the White House disagrees with the GAO opinion that prepackaged video news releases prepared and distributed by Federal agencies or their public relations firms that do not disclose, that this would not constitute illegal covert propaganda.

One of the videos reviewed by GAO was funded by one of your agencies, CMS. Now, again, I don't expect you to have these numbers at your fingertips, but if your staff could take note of this, as the appropriations subcommittee here, could you provide this subcommittee with your anticipated budget for fiscal year 2006 for public relations activities, including any contracts with public relations firms, media buys, et cetera, if you could provide that for the committee.

Secretary LEAVITT. Indeed we will.

[The information follows:]

National *Medicare & You* Education Program Budget

Activity	FY 2005 Appropriation	FY 2006 Estimate	Description of Activity in FY 2006
Beneficiary Materials	$47.9 M ($13.0M UF) ($15.0M PM) ($19.9M MMA)	$43.5 M ($14.0M UF) ($13.0M PM) ($16.5M MMA)	National handbook with comparative information in English and Spanish (national & monthly mailing); *targeted materials only to the extent that funding is available after payment of the handbook.*
1-800 MEDICARE (toll-free line)	$181.6 M ($61.0M PM) ($120.6M MMA)	$173.3 M ($43.8M PM) ($41.8M UF) ($87.7M MMA)	Full call center and print fulfillment services with 24 hours a day, 7 days a week access to customer service representatives for 12 months
Internet	$22.7 M ($9.1M PM) ($3.0M QIO) ($10.6M MMA)	$15.2 M ($9.0M PM) ($3.0M QIO) ($3.2M MMA)	Maintenance, updates and enhancements to existing interactive databases and web sites; software licenses.
Community-Based Outreach	$48.8 M ($16.0M PM) ($32.8M MMA)	$45.1 M ($13.2M PM) ($31.9M MMA	SHIP grants; REACH; and HORIZONS
Program Support Services	$39.45 M ($19.3M PM) ($12.25M QIO) ($7.9M MMA)	$41.15 M ($13.9M PM) ($12.25M QIO) ($15.0M MMA)	Ad Campaign at $22.9M; $12.25M for CAHPS; $6.0M for evaluation & assessment, formative research, and consumer testing
Total	$340.45 M ($120.4 M PM) ($13.0 M UF) ($15.25 M QIO) ($191.8M MMA)	$318.2 M ($92.9M PM) ($55.8M UF) ($15.25M QIO) ($154.25M MMA)	PM – Program Management UF – User Fees QIO – Quality Improvement Organizations MMA – Medicare Modernization Act

Senator HARKIN. I appreciate that.

MEDICARE MODERNIZATION—PART D

Secretary LEAVITT. Senator, I might just comment——

Senator HARKIN. Sure.

Secretary LEAVITT [continuing]. Make one statement that we will obviously follow the guidance of our legal counsel on this matter and make certain that we are acting within the scope of the rules. We have a very demanding challenge in front of us collectively as a government during the next 15 months, and it's the rollout of Medicare Modernization, the Part D for prescription drugs.

One of the—at the base of this conflict was the question of what tools we should deploy and use to provide people with information about their options under Part D. I mention that simply to put some perspective on the dilemma we're facing, reaching people, educating them. We enlist the help of the Senate, and at the risk of eliminating the good reputation I formed with Senator Specter on stopping when that red light goes on, I'll quit there.

Senator HARKIN. Well, Mr. Secretary, just summing up, we send out letters and information to our constituents all the time, but we sign our names to it, you know, and I'm certain those who in my State who disagree with me dismiss it because I've said it, and you know how that goes. But at least they know where it comes from.

Secretary LEAVITT. Right.

Senator HARKIN. Do you think that any information provided by HHS should be attributed to HHS? I mean, I realize you're going to get information out, but at least it ought to say where it comes from.

Secretary LEAVITT. That seems like a logical statement to me. I don't know the nature of this dispute. I know that there has been discussion between GAO and differences of opinion about it. At this point, our role is to first of all do the best job we can in being able to educate people on the opportunity that's there and at the same time make certain we're within the rules. I can assure you we'll do our best to stay within them.

Senator HARKIN. I thank you. We will, as I said, when you send those anticipated figures up, any contracts you have with media firms and stuff like that, we would like to analyze that closely.

Secretary LEAVITT. Thank you.

Senator HARKIN. Thank you, Mr. Secretary. Thank you, Mr. Chairman.

Senator DEWINE. Senator Craig.

STATEMENT OF SENATOR LARRY CRAIG

PANDEMIC FLU VACCINE

Senator CRAIG. Thank you very much, Mr. Chairman. I would hope that any activity or publicity that has been garnered as a result of certain advertising and information flows does not put a chilling effect on what I believe is a fundamental responsibility of the agency to communicate with the public, and to do so in a forthright and direct way. Clearly as we struggled to bring folks on line with the prescription drug card and to get them into the system so that as we roll out the plan as you're talking about, there clearly needed to be an informational flow. There was a partnership at AARP at that time that was a cooperative effort, Mr. Secretary, that I think worked extremely well.

So while I do believe there ought to be full disclosure, I don't think you or I would dispute that, I would hope that anyone who might charge that you're doing something beyond without good grounds, this Senate spends a lot of time and money getting out our point of view, and more importantly, once a policy is developed and ready for the public, I think it's important that we communicate it effectively.

FLU VACCINE

One question of you: Last year I wore a different hat than I wear today, and that was chairman of the Select Committee on Aging—Special Committee on Aging. We spent a lot of time prior to and after the announcement by Chiron that they had been forced to close their Liverpool plant and could not supply to the marketplace and to Americans the necessary flu vaccine that we had antici-

pated. We worked very closely with your predecessor in making sure that somehow we made it through, and we are making it through this year it appears. At least thank goodness we have not had a major outbreak, but the flu is out there and it's taking lives as it does.

But I think you are right to be concerned of a pandemic, and therefore, clearly the need in this country to build a reliable supply of flu vaccine. We, by a—for a variety of reasons including liability, while our class action efforts of the past month may help some, we've run a lot of folks offshore or out of business. The business of making vaccines is not 100 percent perfect in all instances. There is liability without question.

Senator Bayh and I have introduced legislation, you're right. There are others who have looked at shaping the market or assisting the market. When we deal with the flu virus, and it is constantly in mutation, you cannot inventory this on the shelf and keep it there. It must be new with the season. You have to have the capability to produce it. I do believe there will come a day when you are right to be concerned about what's going on elsewhere in the world as it relates to flu vaccines. It is a killer of our elderly, there is no question about it.

Could you for a moment spend some time on that issue with us as to what you anticipate you'll be doing? I see the Liverpool plant is back up in operation. It looks like Chiron is back in the market. That's wonderful. But we're still—we still have a very fragile system. We're looking at new techniques beyond the egg to cell for production purposes. Enlighten us if you would as to where you see it at this moment, and what we might do to assist you in ensuring a constant and reliable supply.

Secretary LEAVITT. Judgements on how much and when and what to buy are complex and often times required to be made with incomplete information, or at least imperfect information.

Senator CRAIG. That's right.

Secretary LEAVITT. It's in some respects like many other commodity-type business or business decisions where there are peaks of use and the question as to whether you buy to the peak always or whether you buy what you think will be normal. The truth is they will not be manufactured unless there's a market, and often times government has to be that market. We've proposed in this budget for back-up guarantees some $20 million in 2005 and $30 million in 2006, and also $120 million for pandemic work for alternative production.

I would like to just update you some, Senator, on efforts we are making to follow the avian flu in Asia. We have people on the ground who are now working with various governments in their clinics, in their—working with their governments, with their practitioners. We're trying to deploy more and more resources at the source. Pandemics have occurred on three different occasions during this century. There's no reason for us to believe they won't happen again. They strike quickly. We don't know when they will strike, we don't know where they will strike, and as you've suggested, we don't always know the strain of the flu, and we have to be in a position to respond quickly.

It is a matter of grave concern to me. I am following this literally on a daily basis. I receive a daily briefing now from CDC and others involved. Currently I believe that we are following the right path, but we'll keep you and other members of the committee informed as things develop.

Senator CRAIG. Well, I thank you very much. There are many of us following this. We're glad to see you fully engaged. You've made, in my opinion, the right statement. To ask companies to supply to an indeterminate market means that we have to stabilize the market, and the only way to do that is for government to be the stability. Therefore to, at the end of the cycle, to be able to buy out, if you will, excess, as long as the companies have met the level of projection, is something I think we ought to build a level of expectation for in the marketplace. It's in part why we don't have companies operating today. We bankrupt them by basically suggesting they supply to a market it didn't develop and then we weren't there to sustain them in the end.

So I thank you for that. I'm glad to see there's increased money in the budget for those purposes and that we're moving as well as we can in relation to pandemic knowledge. Thank you.

STATEMENT OF SENATOR MIKE DEWINE

Senator DEWINE. Mr. Secretary, welcome.

Secretary LEAVITT. Thank you, Senator.

COMMUNITY ALTERNATIVE FUNDING SYSTEMS

Senator DEWINE. Ohio's Community Alternative Funding Systems, the CAFS program, serves individuals with mental retardation and developmental disability. However, the CAFS program apparently does not comply with Federal mandates, and as a result, Ohio will not be providing Medicaid services to this fragile population. You and I have talked about this, our staffs have talked about this, and I just want to again mention it to you that as we, Ohio, works its way through this problem, I hope that you will continue to work with Ohio to try to work this out. We understand Ohio has to comply with Federal law, but we need to make this transition as smooth as we can as we find other ways to serve this population. These are kids, these are kids in school, these are kids who really are a most fragile population. So I just look forward to working with you on that.

Secretary LEAVITT. Thank you. May I say that there is no disagreement on the nobility of the purpose and a commitment to find a solution.

MEDICAID FUNDING

Senator DEWINE. Good. We appreciate it. We'll work with you. We appreciate you working with us. Thank you very much.

Last year, one of our Ohio children's hospitals in Cincinnati was pursuing a Federal grant trying to find money to continue a major project in improving the quality, the safety, and the efficiency of its care using technology, best practices, and sound management. But they looked around and they found that really there was no way to pursue Federal funding in regard to kids. It's rather ironic, I

think, that that is true, because if they had been doing it, if it was an adult hospital, they had been doing it, there's Medicare money available. There's not Medicaid money available.

So again we have a situation really where kids are discriminated against. I wonder what you can do to change that in your Department and what you see is the future to try to deal with this.

FLEXIBILITY IN MEDICAID

Secretary LEAVITT. I spoke briefly earlier about what I believe is a wide and broadly held view that Medicaid is rigidly inflexible and that it creates the kind of circumstances—we've talked a couple of times already today about where there are noble causes, noble pursuits that ought to be done, and there's no disagreement on the cause, but people are left without the capacity to respond to it.

That's one of the reasons that we hope very much that the Congress will act to provide more flexibility in Medicaid. I believe one of those areas would be the ability to construct benefit packages that would be tailored particularly in the instances of mothers and children. We believe more flexibility will not result in anything other than more people being covered as opposed to fewer.

Senator DEWINE. Well, this is the type of thing that, you know, our children's hospitals really need the ability to deal with, and I would hope you would take a look at that as we may possibly design something to deal with that.

TREATMENT OF CHILDREN WITH HIV/AIDS

Senator DEWINE. Let me move to another area. Currently few programs specifically target the treatment of children with HIV/AIDS in developing countries. A primary reason is the lack of appropriate pharmaceuticals for use in children. We all of course know that children are not small adults and treating them that way jeopardizes their lives. With 2.5 million children infected with HIV around the world, it's essential that we have appropriate medications to treat them.

How does your budget plan and your Department—how do you plan to ensure that HIV/AIDS drugs, both generic and brand name approved by the FDA expedited process, also include pediatric formulations as well as important dosing information needed for treating different age groups?

Secretary LEAVITT. Senator, NIH has provided $25 million in 2004 and 2005, and they're proposing another $25 million in the 2006 for pediatric drug research. I believe that information on the effects of those drugs in children is critically important as well, and I'm looking forward to working with you to ensure that we have success in this effort.

[The information follows:]

HIV/AIDS DRUGS

On May 17, 2004 FDA published guidance for the pharmaceutical industry encouraging manufacturers to submit marketing applications for fixed dose combination (FDC) and co-packaged versions of previously approved single entity antiretroviral therapies. The guidance encourages the development of pediatric formulations for these products. Also, subsequent to the publication of the draft guidance, FDA expanded the expedited review program to include single product generic applications. Most of the first line antiretroviral agents are currently available in pedi-

atric dosage forms, so these pediatric formulations can be made available through the generic drug approval process.

Regarding fixed dose and co-packaged combination products, only one company thus far has expressed interest to FDA in developing a pediatric combination product. This could be explained in part by the challenges associated with establishing appropriate doses for pediatric patients for a fixed dose combination product. Such combination products generally do not provide the dosing flexibility needed for pediatric HIV therapy. Also, many of the pediatric formulations are in the form of oral solutions that are not amenable to combination product development. Combination therapy in younger pediatric patients might best be accomplished through the use of individually formulated antiretroviral products that can be made available through the generic approval process. The adult combination products can be used in the older pediatric population.

Regarding the application of the Pediatric Research Equity Act (PREA) to PEPFAR (President's Emergency Plan for Aids Relief) applications, the Agency is enforcing PREA for these applications as it would with any other application. However, PREA does not apply to most generic products or co-packaged products. When PREA does apply to a drug (including HIV drugs) we do not hold up approval but grant deferrals as appropriate for these life-saving treatments.

In addition, the pediatric exclusivity provision of the 1997 FDA Modernization Act and the subsequent 2002 Best Pharmaceuticals for Children Act have generated many clinical studies and useful prescribing information for many products, including several for the treatment of HIV infection. FDA has an HIV Written Request Template to facilitate the development of products. Following are a few examples of products that have been approved for treatment of HIV infection in children. These approvals resulted from studies submitted in response to a Written Request from FDA.

Ziagen (abacavir), Zerit (stavidine), Videx (didanosine), and Viracept (nelfinavir mesylate), in combination with other antiretroviral agents, are indicated for the treatment of HIV–1 infection in children. Use of Ziagen in pediatric patients aged 3 months to 13 years is supported by pharmacokinetic studies and evidence from adequate and well-controlled studies of Ziagen in adults and pediatric patients. Use of Zerit in pediatric patients from birth though adolescence is supported by evidence from adequate and well-controlled studies of Zerit in adults with additional pharmacokinetic and safety data in pediatric patients. Use of Videx in pediatric patients two weeks of age through adolescence is supported by evidence from adequate and well-controlled studies of Videx in adults and pediatric patients. Use of Viracept in pediatric patients from age 2 to age 13 is supported by evidence from adequate and well-controlled studies of Viracept in adults with additional pharmacokinetic and safety data in pediatric patients.

In addition, in March 2003, the Pediatric Subcommittee of the AntiInfective Drugs Advisory Committee of the Food and Drug Administration, Center for Drug Evaluation and Research discussed the development of antiretroviral drugs in HIV-infected and HIV-exposed neonates younger than four weeks of age. The Advisory Committee supported the continued need for development of products for neonates.

These are just a few examples that demonstrate FDA's commitment to the principle that product development should include pediatric studies when pediatric use of the product is intended. In addition, through efforts to make safe and effective antiretrovirals available for treatment of HIV across much of the developing world, we expect to reduce the number of children born with HIV infection and thus significantly impact global health.

Senator DEWINE. Good. Well, my time is up, but we hope to continue to work with you on this. Thank you very much. Senator Kohl is gone. Senator Murray.

STATEMENT OF SENATOR PATTY MURRAY

Senator MURRAY. Thank you very much, Mr. Chairman. Mr. Secretary, thank you for being here today. I can't think of an agency that doesn't have more direct impact on lives of every single one of the constituents we represent here, and it's a tremendous job and we appreciate you taking it on.

HEAD START

I do want to make one comment on Head Start. We had a conversation about this before and in a written response you sent to me you said that you are committed to ensuring the implementation of the President's proposals on Head Start that provide an opportunity for more children to be served by local Head Start programs at the highest level of quality.

I liked the statement, but unfortunately the President's proposal does not provide for more kids to be in Head Start, and I just really urge you to go slow on this proposal. If we break the compact that these local communities have in providing Head Start, I think we're going to take away the basic tenet that Head Start was put together on. It's not just an education program. It's making sure that kids are ready to learn when they get to school.

So I just—I ask you again, I will tell you I'm going to be working hard to make sure that we do this right and you'll be hearing more from me on that, because I'm very concerned the President's proposal will eliminate an important compact and just essentially put in another bureaucratic layer of government that won't help any child get to school ready to learn.

MIGRANT HEALTH CENTERS

What I did want to ask you about today, however, is the budget request which we are here to discuss today, and I am very concerned about the mixed messages that we're sending communities. I really appreciate the President's leadership on funding for the community in migrant health centers. I couldn't agree more with the administration's support for these centers, because they do provide prevention-based affordable health care. They're not just a safety net. They really do a good job in providing health care for low income, often uninsured patients that often fall through the cracks in our health care system. So I applaud the administration's request for another $304 million. I think that's great.

But what I am concerned about is a number of the other budget policies that are coming at us will make it impossible for these community health centers to meet their mission and to provide the health care that we're asking them to. The other proposals on New Starts and Medicaid and the elimination of coordination services like the Healthy Community Access Program are going to have a huge impact.

We know that our community health centers are already seeing double digit increases in the number of patients that need care, and as the number of patients uninsured continue to increase, their load is going to continue to increase. We need to make sure that we're not just funding new health centers, but we're making sure that the existing ones get the support they need.

Medicaid on average accounts for more than 30 percent of the revenue for these community health centers, so any policy cuts in Medicaid is going to have a direct impact on that. I'm already hearing from all of my community health centers that they are deeply concerned about the proposed cuts in Medicaid. We're already dealing with a mental health crisis under Medicaid. I think you know CMS just notified Washington State that they can no longer de-

pend on the $82 million annually to provide community-based mental health care for low income patients.

Another policy I'm very concerned about is you talked about providing flexibility, but you're taking away, but that's a point for another day. The community health centers are the ones who are going to absorb the impact of that on them.

Then the elimination of the Healthy Community Access Program that works out in our communities. I know the administration in the past has said it's not effective. I really invite you out to Washington State or to talk to some of our HCAP grantees, because they really are making a difference. Elimination of that is going to be very hard for our community health centers to be able to succeed.

So my question to you is, thank you for providing additional funds, but budget policies that impact these community health centers in very negative ways are going to make it impossible. How do you reconcile increasing the money but passing the policies that make it very difficult for them to be successful?

Secretary LEAVITT. Senator, let me respond on Head Start. I'll go through all of the three areas you talked about. The President's proposal would actually allow for 9,729 additional students to be served by Head Start. The President and the Secretary of HHS are enthusiastic about Head Start and want to make sure it continues not just to serve those, but to expand. I've had a number of meetings now with Secretary Spelling to talk about how we could coordinate activities between the Department of Education and HHS. We think that that will leverage those funds even further.

With respect to health center funds and the whole subject of community health centers, that's another area where we share enthusiasm. We think that the President's proposal puts us again on a path to complete his objective of 1,200 new and expanding centers. This one will add 40 in the areas with the lowest incomes.

We have made a policy decision to emphasize actual service delivery, and there are places in this budget, with health center funds being one of them, where the actual—where by statute only 15 percent of those funds could go for service delivery and went for other matters ancillary to it. So there was a priority put on our part for the actual delivery of funds.

With respect to Medicaid, clearly community health centers are dependent upon continued participation by Medicaid. I think, as you pointed out and others have, that it's nearly 35 percent of their overall budget. We want them to succeed. A cut in the number of dollars in Medicaid would in fact be alarming. However, this budget will reflect more than 7 percent more dollars going into Medicaid than did before. This is not a matter of cutting. We want Medicaid to increase. We want it to increase .2 of 1 percent than what had been proposed before, but there are very few large numbers in the President's budget that will reflect a 7 percent-plus increase, and Medicaid is one of them.

HEAD START

Senator MURRAY. Well, I appreciate your response. I know I'm out of time. I just would ask you again to go cautiously with Head Start, because it is more than just an education program, and it is a success story, and I want to make sure we don't undo that.

I just am concerned that if we just focus on new community health centers we are going to leave the ones that are out there not doing a good job and then we'll be back here saying, well, they don't do a good job, let's not fund any of them, and I don't want to go there. I think it's really important to understand the health care impact, the crisis, the budget numbers that are hitting these, the number of uninsured that are increasing, and we need to be able to do our part here. I will continue to work on that. I know you care as well, so thank you very much.

Secretary LEAVITT. Thank you.

Senator DEWINE. Senator Durbin.

STATEMENT OF SENATOR RICHARD J. DURBIN

Senator DURBIN. Thank you very much, Mr. Chairman. George Carlin is a great observer of life and has a routine relative to riding on airplanes, most of which cannot be repeated at this hearing.

But there is one thing he observes: When starting to land in an airplane, the flight attendant says, let me be the first to welcome you to Washington DC. Carlin asked, if you're on the same plane I'm on, how can you be welcoming me anywhere? I would like to welcome you to this committee, but since this is the first time I've ever been on this committee, I can't. I'm just happy to be here with you today.

Secretary LEAVITT. Thank you.

MEDICAID AND MEDICARE

Senator DURBIN. I can't officially welcome you, but I've wanted to be on this subcommittee for a long time and I'm glad that it finally happened. It's very critical and important.

SOCIAL SECURITY

The President is on a 60-day tour around America to cities to talk about the crisis or challenge or problem, or whatever is the word du jour of Social Security. There are many of us who believe that Social Security does present a challenge that we should address and address now with sensible, common sense approaches that over the long term will help us meet our needs.

I'd like to show you a chart though that compares the challenge of Social Security to other challenges. I'll make sure the Secretary can see it there. You'll note on this chart that over the period of time of our debate about the costs of Federal programs, we anticipate by 2075 a 48 percent increase in the cost of Social Security as a percentage of our gross domestic product. Look at the numbers for Medicare and Medicaid, dramatically larger, 318 percent for Medicare, 342 percent for Medicaid.

So if the President is looking down the track and seeing 40 or 50 years from now this light of a train coming toward us and warning us about this, certainly we should be sensitive to the fact that looming directly behind us is a locomotive that says health care in America that is about to run us over.

You are addressing through this budget some of the cost of programs like Medicaid and Medicare. Neither this administration nor this Congress apparently has the political will to address the much

larger issue we face in this country. If there were another line in this chart, the cost of health insurance by the year 2075, it might even be larger in terms of increase. So how can we address these things so tentatively in such a piecemeal fashion and expect to really resolve the difficulty?

AFFORDABLE HEALTH INSURANCE

I just left a meeting with the President of one of the largest unions in America. He says we're about to lose manufacturing through his union because of the cost of health care. I hear that from small and large businesses alike. Yet we're not talking about it. If the President were making a 60-day, 60-city tour about what to do to make sure that every American had affordable health insurance that provided basic protection for their family, he would have turnouts, unimaginable turnouts of people interested in this issue.

MEDICAID

So I ask you this. What is—what do you think we should do in this next year? Is the answer to cut coverage on Medicaid? Every time someone in Washington says flexibility, I grab my wallet, because flexibility means less money, I know that, I've been around here long enough. I understand we need to change some rules, but I'm afraid flexibility is just a cover for a reduction in cost.

Shouldn't we be asking for some advantage for consumers and taxpayers in this process? We're still in a position where Medicare cannot bargain under the new prescription drug plan to bring pharmaceutical costs down. Medicaid in most States is really limited as to how it can bargain with drug companies to bring the cost of drugs down for recipients in those States. Yet we know over the border in Canada drugs are a fraction of the cost.

How can we be honest and sincere about dealing with health care if all we're going to do is cut benefits for poor people and not address cost issues such as the ones that I just mentioned?

Secretary LEAVITT. Senator, I've become fond of observing that there is a point in the life of every problem when it's big enough you can see it but small enough you can still solve it. Your chart reflects three of them. The President has clearly taken two of them on this year. That's—two out of three is a very significant undertaking.

But the matter that you've reflected on, health care costs, clearly is one that we will all have to deal with. Now I, recognizing the limit of time, may I just say—point out four things that I believe can and should be done in this budget year to get us started?

MEDICAID REFORM

One is in fact Medicaid reform. These are reforms that will not result in anyone losing health insurance, but in fact will allow us to preserve health insurance for many who have it and who are at risk of losing it, and I believe would have the capacity of expanding health care to others for reasons that I've already enumerated and won't repeat.

HEALTH IT

The second is health IT. I believe health IT is the new frontier in health care productivity. Many things in this budget would point us toward being able to harness the powers of technology.

But it leads us to, I think, a third, and that is we're measuring the wrong thing. We measure quantity of care, not the quality of care. We are not measuring outcomes. And I believe until we begin to measure performance outcomes and compensate providers and others on the basis of those outcomes, we will continue to see an unsatisfying result.

ACCESS TO HEALTH INSURANCE

The fourth would be expanding health care to—or access to health insurance. The President's proposal would allocate $125 billion over the next 10 years and would result in 12 to 14 million people who currently do not have coverage to receive it. So Medicaid reforms, IT, pay for performance, and expanding access to health insurance through health savings accounts and other mechanisms I believe would be at least steps in the direction that you've pointed.

Senator DURBIN. I think they are steps in that direction. There may be some different—I don't know if association health plans is part of what you're suggesting here. They raise a lot of questions about standards and actual coverage and the like and the financial stability of the company's offering.

HEALTH SAVINGS ACCOUNTS

Health savings accounts again have been a wildly popular theory here since Golden Rule Insurance Company became the favorite of then-Speaker Gingrich. We keep hearing about it every year. I'd like to see some demonstrated proof that it really does offer the kind of health insurance coverage that we want to see in the long term.

I don't know, Mr. Chairman, if my time is expired here.

Senator DEWINE. Why don't you just continue.

Senator DURBIN. Thank you.

Senator DEWINE. Because I'm going to have some questions too, so why don't you just go ahead.

Senator DURBIN. Well, thank you very much.

Senator DEWINE. As long as the Secretary has a couple more minutes.

TITLE X

Senator DURBIN. I will just try to make it as direct as I can and as brief as I can. Let me talk to you about Title X. Title X, of course, is the family planning program, particularly for low-income people. If there's one thing that divides this Congress and this Nation, it is the question of abortion, and we have spent more time and anguish over this issue, what is the right thing to do. Most people would conclude that the right thing to do is to give to that prospective mother and father the option of planning their family so that they don't find themselves in a position where there are un-

intended or unplanned pregnancies forcing decisions which may lead to abortion.

I take a look at where we are today. Your fiscal budget for 2006 flat funds Title X family planning programs at $286 million. This level of funding does not keep up with inflation and meets the needs of fewer than half of the low-income women who qualify. If we are truly trying to reduce the number of unintended pregnancies and abortions, how can we do it with a budget that does not meet the obvious need for family planning information, counseling, medications for the lowest income people in America?

Secretary LEAVITT. Senator, you're correct in that the budget between 2005 and 2006 is the same. That follows, however, a year where we did increase our proposal by $10 million. I'd also point out the fact that the Federal share of Medicaid during that period of time who served that same group went up $65 million, and the Indian Health Service went up $19 million.

So while that one category may have been level, the broader view was up $84 million on——

Senator DURBIN. On Medicaid as opposed to Title X.

Secretary LEAVITT. On Medicaid and Indian Health Services, and they serve basically the same population.

Senator DURBIN. I would not disagree, but certainly that money is being spent on many, many other things, not focused as Title X is on family planning.

Let me ask you in the same vein, most parents that I know, certainly my family, raising children preached abstinence, saying to these children, my children and many other children, wait, don't make a mistake, make the right decision and have enough respect for yourself to make that right decision. That has become such a major part of our effort now in trying to reduce teen pregnancy and unintended pregnancy.

ABSTINENCE

The proposed budget includes a $38 million increase for abstinence only until marriage programs. The groups that have taken a look at this, like the National Academy of Sciences' Institute of Medicine, have criticized this investment in these abstinence-only programs. Some investigations by the House Committee on Government Reform have found that the abstinence-only programs contain errors and distortions in the messages that they are giving to people and young people. One federally funded curriculum, for example, was found to be teaching students that sweat and tears are risk factors for HIV transmission, which I don't believe any reputable medical doctor would agree with.

So I ask you, when it comes to these abstinence-only programs and the amount of money that we're putting into them, do you believe that this is our best investment in terms of good public health policy to reach the goal of educating young people so that they make the right decisions about their own bodies?

Secretary LEAVITT. Senator, we serve many populations in many different ways. This is a commitment on the part of the administration to teach one principle that we know is true, and that is abstinence is 100 percent effective. I also recognize that there are times when one program or another will have the validity of one fact or

another or approach on all sides of the ideologic spectrum, and we ought not to be defending things that aren't true in any of those.

We need to have a commitment to the truth, and the President's commitment to include abstinence-only programs is real, because he believes, as do I, that it is in fact what we ought to be teaching our children.

Senator DURBIN. I don't quarrel with that premise, and as I said, most parents start there. Some parents and teachers and counselors and ministers come to the conclusion that more has to be said beyond "say no." So I won't go any further than to say I hope that we will test each of these programs to make sure that the information given is accurate and then be honest about the outcomes.

DIETARY SUPPLEMENTS

My last question if I might ask relates to dietary supplements. I've had a passion over this industry and the laws regulating it. I got up this morning and I took my vitamins, for the record, so I am not opposed to taking vitamins. I think it's good, it's healthy. I don't think it's going to hurt me. Maybe it'll help.

But some of these dietary supplement companies are selling products that have never been tested. They are making claims about their products' efficacy which they cannot substantiate. They are marketing their dietary supplements to children. The ephedra scandal of just a year or so ago is an indication of that element of the dietary supplement industry that was clearly doing all the things that I just mentioned to the detriment of the health of America.

Senator Hatch and I have debated this back and forth. We don't see it all the time eye to eye, but we have come to a conclusion, and I hope that you will consider supporting it, and that is that the dietary supplement industry should at a minimum make adverse event reports to the Food and Drug Administration. If some company is making a dietary supplement that results in a bad health outcome, a seriously bad health outcome or death, that should be reported to the Food and Drug Administration. That is not the law today.

What is your opinion? Do you believe that those who are marketing dietary supplements should be required to report adverse events to the Food and Drug Administration as those making over-the-counter drugs and pharmaceuticals are required?

[The information follows:]

DIETARY SUPPLEMENTS

With enactment of the DSHEA, Congress made the decision to create a new regulatory regime for dietary supplements modeled more on the Agency's regulation of food safety and less on the drug regulatory model. With the exception for new dietary ingredients, FDA's regulation of dietary supplements is essentially post-market program similar to food regulation.

Under the Dietary Supplement Health and Education Act (DSHEA), FDA relies on voluntary adverse event reports as a major component of our post-market regulatory surveillance efforts. Voluntary reporting systems are estimated to capture only a small percentage of adverse events, but they provide valuable signals of potential problems. When such a signal identifies a possible safety hazard, the burden is on FDA has the ability to gather and evaluate any scientific literature or information regarding whether the substance produces a safety hazard FDA has used this information to open investigations that led to removal of ephedra from the market and is currently investigating the marketing of steroids as dietary supplements.

FDA's enforcement actions are enhanced by a close working relationship with DEA, the FTC and other State and Federal agencies.

Another important aspect of FDA's regulatory and surveillance programs are current good manufacturing practice (cGMP) requirements for dietary supplements authorized in the Act. These regulations will establish industry-wide standards to ensure that dietary supplements are not adulterated. This final rule is in the last stage of review and is expected to be published in the near future.

In addition, FDA has a post-market surveillance program to support enforcement of labeling requirements for dietary supplements. This compliance program, Dietary Supplements—Import and Domestic, contains guidance to FDA field offices regarding field exams and sample collections to determine compliance with the labeling requirements for dietary supplements. Significant violations of the labeling requirements for dietary supplements may lead to an advisory action, such as a Warning Letter, or to a court action for seizure or injunction. Imported products that do not comply with FDA labeling requirements are subject to detention and refusal when offered for entry into the United States.

FDA will continue in its efforts to take action against dietary supplement products that threaten the public health and will continue to provide guidance to the industry and outreach to consumers in this regard. We further believe that the promulgation of the GMP rule with provide another measure of safety for dietary supplements, and we look forward to working with the Committee to further examine these issues and ensure that appropriate steps are being taken.

Secretary LEAVITT. Senator, I have not had the benefit of being able to hear you and Senator Hatch debate these issues. It sounds like a colorful and rather interesting thing to hear. I'll look forward to hearing more—to find that the two of you have agreed on this. Sounds like something I ought to learn about.

Senator DURBIN. Let me share it with you. I won't put you on the spot any more on this, but I hope you'll take a look at it. It could be a reasonable way to bring some regulation to an industry which by and large is doing a wonderful job, but there are some players in this industry who are not.

Mr. Chairman, thank you for your forbearance and patience, and Mr. Secretary, thank you for being here.

OLMSTEAD ACT

Senator DEWINE. Mr. Secretary, just a few more questions. President Bush signed an executive order in response to the 1999 Supreme Court decision in regard to the Olmstead Act. This Court said that the disabled have a right to live in a group home or other supportive system rather than being pushed into an institution, and the Court directed the government to develop opportunities for the disabled to better live in their communities. The Court also said forcing them into institutions is discriminatory.

The executive order told the agencies to put together plans to make this happen. How are you proceeding in reaching this goal?

Secretary LEAVITT. Senator, it would be better if I could provide you with specifics. The actual plan and the execution of that plan inside either our agencies our broader would be unknown to me. But I would like to point out that the President's money follows the person it is designed specifically to——

Senator DEWINE. That was my next question anyway.

Secretary LEAVITT. Good. Well——

Senator DEWINE. We can—you can proceed.

Secretary LEAVITT. One of the——

Senator DEWINE. But you will give us, Mr. Secretary, you can follow up then in regard to this question about——

Secretary LEAVITT. Yes.

Senator DEWINE [continuing]. What the plan is and what the timing would be on that.

Secretary LEAVITT. We will be responsive on that query, and I'll also point out as one of the specific Medicaid, for example, proposals that we would like to see adopted this year would be a capacity, a flexibility, again stepping away from the rigid inflexibility that is currently there to serve those who are disabled and particularly those who are elderly.

Medicaid is a good example of a policy that just needs to be changed, needs to be modernized. Medicaid was established in the 1960s. The state of practice at that point was to institutionalize basically those who were either disabled or elderly and disabled, and consequently Medicaid, without some waiver or without a change in the law, simply doesn't allow us to pay for any circumstances outside an institution, and that just needs to change. It's making the point that you have and we hope very much that Congress will act with some dispatch to give States that capacity.

DISABLED

Senator DEWINE. Your President's proposal and your budget, the money following the person, I wonder if you could elaborate on that in regard to how that will affect the disabled, and specifically how that will work in the 50 States. Are we talking about 50 State programs, or how will that blend with national uniformity and how these programs will be administered?

Secretary LEAVITT. Well, specifically it would create——

Senator DEWINE. This is—my understanding of this—excuse me—this is a—these are pile-up programs.

Secretary LEAVITT. That's right. It would create a 5-year demonstration that finances services for individuals who are in transition from institutions to the community. The Federal Government would fund 100 percent of the community-based services for the first year and then funding would revert back to the States at the current Federal match, which means the Federal Government on average would pay about 65 percent.

The demonstration would test whether the increased use of home and community-based services would reduce spending on institutional care as the advocates and as this Secretary believes that it will.

Senator DEWINE. How will that work in regard to the disabled community? I mean, this is designed in my understanding for the disabled community but also for older Americans. Is that correct?

Secretary LEAVITT. Well, the rationale of the program is that the proposal would encourage States to move from institutionalizing long-term care patients who are served by Medicaid into home and community services, which in turn may reduce the spending on institutional care. The proposal is an attempt to rebalance the system, as I've indicated, where long-term care has been essentially institutionalized under the Olmstead decision by increasing the care-setting choices and assisting individuals with disabilities. They will be able to live in the home and community-based settings.

This is where they want to be served. Frankly, it's where their families want to serve them. It leverages the great American asset

of people loving their families and choosing to care for them and it helps in the right spot. Disability groups have been very supportive of this and we'll continue to work closely with them and with you on various proposals as we learn more.

Senator DEWINE. Mr. Secretary, I'd like to commend FDA's actions in quickly enacting Best Pharmaceuticals for Children Act, as well as a pediatric rule. How those two programs interact can sometimes though be very tricky, but they interact nevertheless, and that's what they were designed to do.

[The information follows:]

BEST PHARMACEUTICALS FOR CHILDREN ACT

The BPCA is a critical tool in NIH's effort to ensure that adequate information is available concerning the effects and efficacy of pharmaceuticals in children. The NICHD is working with the FNIH and the Secretary to implement the provisions of the law, and to facilitate the testing of drugs.

BACKGROUND

The Best Pharmaceuticals for Children Act (BPCA) established procedures to identify health risks and effectiveness of drugs in children. The Secretary delegated the functions of developing the priority listing of drugs to be tested to NIH and FDA, and the program for testing those drugs to NIH. Dr. Zerhouni delegated the NIH duties to NICHD. Over the last few years we have had several communications with Sen. DeWine's staff about implementation issues. Most recently, they have raised questions about the testing of a particular on patent drug, Baclofen, which is proposed for treatment of spasticity in children with cerebral palsy.

BPCA

Under the BPCA program, different procedures are followed for testing on- and off-patent drugs for pediatric use and labeling. Following the BPCA's enumerated procedure for on patent drugs, NICHD tests a drug only after the manufacturer and current patent holder decline a request from the FDA to conduct the testing and after private donor decline to provide support through the Foundation for the National Institutes of Health (FNIH). (NICHD and FNIH have a Memorandum of Understanding in place to conduct the testing.) If the FNIH is unable to raise sufficient private funds to support the requested testing, and so-certifies to the Secretary, the Secretary refers the drug to NICHD for inclusion on the BPCA program priority list of drugs for testing in children.

ON-PATENT DRUGS

Senator DEWINE. I'd like to bring an issue to your attention. My staff has already raised this with NIH. And that is the on-patent drugs that are currently awaiting study in the NIH Foundation. The pediatric rule provides for the rule to be invoked when a Secretary makes a certification regarding insufficient funds. Preliminary discussions have suggested this would be an appropriate action for HHS, FDA, and NIH to take.

I'd ask that you have your staff take a look at this issue, you take a look at it, and get in touch with the appropriate staff at NIH and FDA and begin the process of invoking the pediatric rule so clinical trials can begin. I would ask you do this and get back in touch with me in regard to this so we can get some resolution and move forward.

Secretary LEAVITT. I will do so, Senator. Thank you.

GLOBAL AIDS FIGHT

Senator DEWINE. I appreciate it. Let me turn if I could to the CDC's work in the global AIDS fight, and you and I have talked

about this before. Specifically in the countries, the non-focus countries, countries such as India and China, let me ask you, does the CDC's global AIDS program do you believe have the infrastructure necessary to expand its programs in these non-focus countries? If not, what's needed to expand their response?

Second, let me ask you, will you support providing increased program support and resources to the global AIDS program and other HHS programs that are part of the emergency plan?

Secretary LEAVITT. The President has made a commitment to expand appropriations to $15 billion to undertake that challenge. Obviously that will need to include the deployment of proper infrastructure in those countries as well as others. We're working hard now to target our efforts to provide for the greatest possible need. We've laid out a series of principles and we're working to follow those principles.

Senator DEWINE. I look forward to having further discussion with you in regard to this. It is a very difficult question, as I think your answer would indicate. Taking the finite resources that we have, even though this administration has made a major commitment, which I commend the administration for, and the Congress has done the same, when you look at the need, it's still finite resources, and trying to make a determination of how aggressively we move into countries like India and China is a very, very tough call.

But, you know, if we don't—if the world does not stem the emerging AIDS problem in India or China or Russia, the ramifications are going to be absolutely unbelievable. When it moves, AIDS moves in India, for example, into the general population, the results are going to be absolutely devastating, and it's getting very close to that.

So it's, you know, these are just tough questions, they're tough calls. I just look forward to working with you and sharing ideas.

Secretary LEAVITT. Thank you. I look forward to the same interaction.

Senator DEWINE. I appreciate it. Well, Mr. Secretary, we thank you very much for your time and attention and look forward to working with you on many issues.

Secretary LEAVITT. Thank you.

SUBCOMMITTEE RECESS

Senator DEWINE. Thank you very much Mr. Secretary.

The subcommittee will stand in recess to reconvene at 9:30 a.m., Wednesday, April 6, in room SD–124. At that time we will hear testimony from the Honorable Elias Zerhouni, Director, National Institutes of Health.

[Whereupon, at 11:45 a.m., Wednesday, March 16, the subcommittee was recessed, to reconvene at 9:30 a.m., Wednesday, April 6.]